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May 27, 1999

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services, Room 1-23  
12420 Parklawn Drive  
Rockville, MD 20852-1745

Re: DOCKET #99P-1340/CP1

Dear Sir or Madam:

I am writing in resolute support of the petition sponsored by the Environmental Health Network of California (received by the FDA on May 11, 1999) to have Calvin Klein's ETERNITY Eau de Parfum declared **misbranded**. According to your own regulations (21CFR 740.1, 740.2, 740.10 of the Federal Food, Drug and Cosmetic Act), "Each ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing. Any such ingredient or product whose safety is not adequately substantiated prior to marketing is **misbranded** unless it contains the following conspicuous statement on the principal display panel: 'WARNING -- The safety of this product has not been determined.'"

Recent gas chromatography studies performed on ETERNITY by two different laboratories on two different samples (sent in their original packaging) indicate that ETERNITY contains 41 chemicals.

- Two were listed as respiratory sensitizers.
- At least five have the potential for Central Nervous System effects.
- At least two are suspected carcinogens.
- One may provoke fetal effects.
- Virtually all ingredients are general irritants.

It is clear that the chemical, physical and toxicological properties of the ingredients in this fragrance formulation, have not been thoroughly studied for their full range of (synergistic) effects. Evidently the safety of this product is unsubstantiated, yet it does not currently carry a conspicuous statement of warning, as required by 21CFR740.10.

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I believe that fragrance safety will replace the issue of Environmental Tobacco Smoke as a major public health priority for the new millennium. Although scents are viewed as benign by unsuspecting consumers, in reality, they are toxic sensitizers and potent indoor air pollutants that must not escape your scrutiny. In 1989, the National Institute of Occupational Safety & Health (NIOSH) recognized 884 poisonous substances (many synthetically derived from petrochemicals) from a list of 2,983 chemicals used in the fragrance industry. Some of them are capable of causing cancer, birth defects, central nervous system disorders, allergic respiratory reactions, skin and eye irritations. In tests conducted at Anderson Laboratories of West Hartford, Vermont in 1998, researchers determined that emissions from fragrances caused various combinations of Sensory Irritation (a brief breath holding at the end of inspiration - a reflex caused by activation of trigeminal nerve endings in the eyes, face, nose and throat of test mice), pulmonary irritation and decreases in a Functional Observation Battery (FOB) indicative of neurotoxicity. It should be noted that chemicals that stimulate the trigeminal nerve system have the capacity to trigger not just the irritant trigeminal effects mentioned above, but also excessive neurological firing and excitotoxicity in vulnerable individuals leading to attention deficit disorders, disorientation, spaciness, memory problems, concentration difficulties, mental confusion and cognitive deficits. Indeed, James Cone, M.D., M.P.H., a Berkeley-based indoor air quality consultant and former Chief of the Occupational Health Clinic at San Francisco General Hospital describes fragrance chemicals as one of five major contributors to indoor air pollution.

Given this scientific evidence, it should be clear that fragrances pose a significant access barrier to educational, employment, entertainment, healthcare, religious worship, and travel activities, for a growing subset of the population who have already become sensitized to scents. Just as cigarettes carry warning labels, consumers have a clear-cut right to be forewarned about the carcinogenic, neurotoxic, and teratogenic chemicals, the respiratory irritants and the sensitizing agents that comprise fragrance formulations.

The history of environmental and occupational health provides a host of examples in which entire industries have acted in complete disregard of public health risks and in which government failed to act until well after disasters were apparent (DDT, asbestos, tobacco smoke, dioxin, PCBs, vinyl chloride, flame retardants in children's sleepware, Chlordane, Alar, urea formaldehyde foam). May I respectfully remind you that protecting the American public is your constitutionally designated duty. I urge you to label ETERNITY **misbranded** and fulfill your constitutional mandate.

In closing, I will leave you with a quote from Seneca, the great Roman author of tragedies, who nearly 2,000 years ago wrote:

***"Our posterity will wonder about our ignorance of things so plain."***

Sincerely,

  
Irene Wilkenfeld

Environmental Health Consultant

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